MARYLAND HEALTH CARE COMMISSION

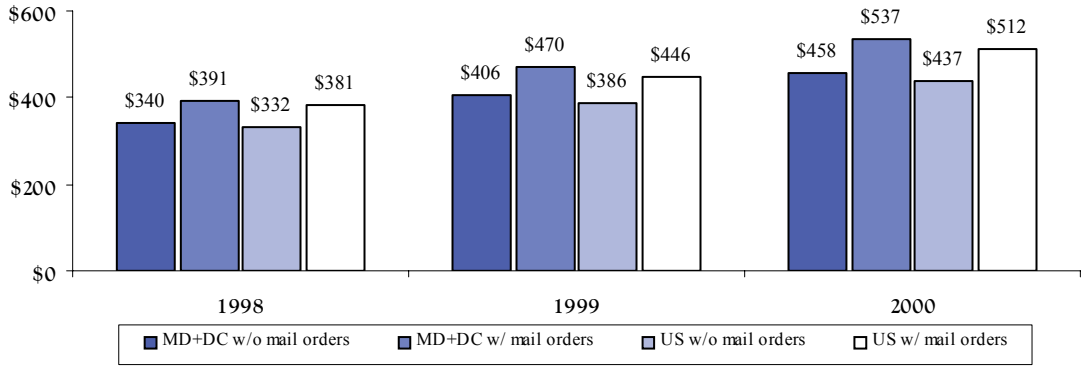
SPOTLIGHT ON MARYLAND

Higher Prices and Increased Use Fuel Higher Pharmaceutical Spending

Consumer spending on prescription drugs in Maryland and the District of Columbia combined (MD+DC), not including mail order channels, reached an estimated $2.7 billion in retail sales in 2000; a 15 percent increase over 1999.[1] Nationwide, non-mail order retail prescription drug sales grew by 14 percent, with over $120 billion in sales.[2] If the mail order share of national retail prescription sales is assumed for MD+DC, estimated retail sales reached $3.1 billion, more than a 16 percent increase over 1999.[3] Comparable national figures are $141 billion in retail sales and slightly less than 16 percent growth over 1999.[4]

Per capita sales for Maryland and the District of Columbia combined indicate about average growth in prescription drug expenditures. Per capita non-mail order sales for MD+DC in 2000 are $458, up nearly 13 percent since 1999, compared to US figures of $437 and over 13 percent. Our analysis of prescription drug utilization among non-elderly Maryland residents with prescription drug coverage showed a similar trend. The average per capita annual spending in this insured population grew by slightly more, 14 percent, to $546 per recipient of at least one covered medication.[5] This growth illustrates that increased drug spending occurs among all ages, not just the elderly. The average number of different drugs used throughout the year showed very little increase, suggesting that more expensive drugs, rather than more drugs, account for much of the increase.

Per Capita Retail Sales of Prescription Drugs, 1998 - 2000[1]

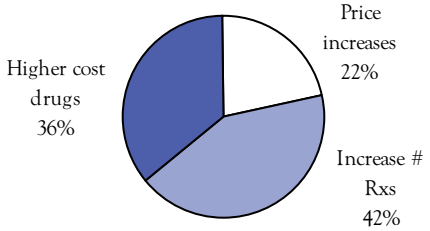


Based on sales with a known source of payment, MD+DC has a higher average prescription price but a lower per capita number of prescriptions compared to national averages. In 1999 MD+DC's average price per prescription was 9 percent above the national average: $46.11 versus $42.27, while the average number of prescriptions per capita for MD+DC was nearly 14 percent below the national average: 8.4 versus 9.8. From 1998 to 1999 the number of prescriptions per capita increased by about 8 percent both in MD+DC (7.7%) and nationwide (8.2%). But prescription price growth over this period was lower in MD+DC (6.7%) than nationwide (9.9%).

Factors Influencing the Increase

Increases in retail pharmaceutical spending can be attributed to consumer demand for prescription drugs, price increases for existing drugs, and costs of newer, higher-priced drugs replacing older, less-expensive drugs.

Increase in Retail Rx Drug Spending, 1999-2000[6]



According to a study by the National Institute for Health Care Management (NIHCM), increases in number of prescriptions dispensed in 2000 accounted for 42 percent of the rise in drug spending, while newer, more-costlier drugs contributed 36 percent, and prices increased 22 percent.[6]

Price Factor: Cost Increases Fueled by New Drugs

Most of the top-selling prescriptions are newer, higher-priced brand name drugs. NIHCM reports that total retail sales of all prescription drugs in 2000 increased 19 percent over 1999. Sales of the top 50 drugs accounted for 44 percent of total retail sales compared to 40 percent in 1999, representing a 30 percent increase in total retail sales. Average retail price of all prescription drugs rose nearly 11 percent from 1999 to 2000, from $40.96 to $45.27, while average price for the top 50 drugs increased more than 9 percent from $61.41 to $67.15. In 2000, retail pharmacies dispensed approximately 2.9 billion prescriptions compared to 2.7 billion in 1999, over 7 percent increase. Increases in utilization

among the top 50 drugs grew by almost 19 percent in 2000, while all other drugs accounted for slightly over 3 percent increase in prescriptions dispensed.

If allowed to compete with more expensive brand-name medicines, generic drugs would significantly reduce the rise in prescription drug spending. On average, generic equivalents cost 30 to 70 percent less than their brand-name counterparts. However, loopholes within the system allow manufacturers of brand-name drugs to keep generics off the market. One technique drug companies use to fend off generic alternatives for their drugs is a practice known as "patent stacking." Just as the patent for a drug is about to expire, the company essentially gets a new patent on the same drug, but in a slightly different form. This may be a form that extends the duration of the drug's effect, such as working for a week instead of a day. In some cases the companies have obtained patents on what their drugs become in the body after a person swallows it. These new patents are for "cosmetic" changes, not for innovations in the effect a drug produces.[7]

However, some consumers fail to make use of generics when they are available. Among persons in the Commission's Medical Care Data Base (MCDB) who made use of their drug coverage, 20 percent of those aged 6-64 filled a prescription for a traditional non-steroidal anti-inflammatory drug (NSAID) in 2000.[8] The patents for all of the traditional NSAIDs have expired, so every drug has a generic equivalent, and since the therapeutic range for NSAIDs is wide, nearly all users will achieve the desired effect with a generic version. However, more than 1 in 5 of the prescriptions for traditional NSAIDs were for brand-name drugs, and branded drugs accounted for the majority of expenditures. The average expenditure for the branded NSAIDs was more than five times the average cost of the generics. For those without prescription coverage, the expenditure difference would be even greater because these patients cannot benefit from the steep discounts negotiated by prescription benefit managers.

Utilization of Generic & Branded Traditional Non-steroidal Anti-inflammatory Drugs (NSAIDs) by Insured, Non-elderly Patients, 2000

	NSAIDs	
Utilization Measure	Generic	Branded
Distribution of transactions	78%	22%
Distribution of expenditures	39%	61%
Average expenditure per transaction	$13	$78
Distribution of persons*	85%	21%

* 6% received generic and branded

Higher Utilization – Driven in Part by Advertising

One of the major factors responsible for the continued growth in prescription drug spending has been marketing to physicians and consumers by drug companies. Direct-to-consumer (DTC) advertising has become an increasingly important mechanism for companies to increase demand for their drugs. According to a study by NIHCM, drug companies invested 16 percent of their marketing budgets in 2000 – $2.5 billion – in DTC, a growth of 35 percent from 1999 and a three-fold increase in DTC spending since advertising guidelines were first issued in 1997 by the FDA.[9] DTC ads are designed to make patients believe a particular drug is best for their condition. As a result, doctors are under added pressure to prescribe specific medications requested by their patients. Two recent surveys indicate the investment in DTC has clearly paid off for the drug companies. In a Kaiser Family Foundation survey, 63 percent of responding physicians indicated that drug advertisements had influenced their patients to initiate talks about specific diseases or treatments at least "somewhat often". Preliminary results from an FDA survey indicate that nearly 25 percent of patients have asked their physicians for a specific brand-name drug, and 69 percent of these patients received a prescription for that drug. As a result, the 50 drugs most heavily advertised in 2000 had increased sales of 32 percent and accounted for almost half of the increase in drug spending in 2000, while sales for all other drugs increased 14 percent.[9]

But are advertised medications really more effective than older, less expensive drugs? Recent news stories have pointed out that some of the new, most heavily advertised drugs provide little or no additional benefits to patients over older alternatives, but cost many times more and, in some cases, bring other risks.[10] The COX-2 inhibitors are a good example of these problems. No more effective at pain relief than traditional NSAIDs, COX-2 inhibitors, such as Celebrex and Vioxx, are purported to be gentler on the stomach. The FDA, however, finds only Vioxx has demonstrated a "lower risk of causing ulcers, gasterointestinal (GI) bleeding and related digestive tract disorders" compared to older NSAID drugs. But recent studies indicate that Vioxx has a higher risk of cardiovascular events compared to Naproxen, an older NSAID, so those at risk for GI bleeding may be better off with a different class of pain reliever altogether.[11] The COX-2s cost about 8-10 times more than traditional NSAIDS for those without insurance.[11]

Utilization of Prescription Drugs by the Insured, Medical Care Data Base, 1999-2000

2000 Average / Change: 1999-2000	COX-2 Inhibitors	2nd Generation Antihistamines		Insured Drugs
	Adults 18-64	Children 6-17	Adults 18-64	Ages 6-64
Number of recipients, % change	95%	15%	15%	-4%
~ Annual medication days supplied ~				
Average per recipient	104	76	90	N/A
Change per recipient	44%	19%	11%	N/A
~ Total expenditures (insurer + patient) ~				
Average per medicated day	$2.40	$1.75	$1.84	N/A
Average annual per recipient	$248	$133	$166	$546

Manufacturers market COX-2s as suitable for anyone needing an NSAID, but only 4-5 percent of all patients needing an NSAID for pain relief are at risk for GI bleeding, and most of these are elderly.[10, 12] Based on the ads, many patients mistakenly conclude that COX-2s are more effective than traditional NSAIDs. Consequently, use of COX-2s has skyrocketed since they were introduced in 1999, even among the non-elderly where fewer than 4 percent are at risk for GI bleeding. The number of non-elderly adult prescription recipients in the MCDB who obtained a COX-2 inhibitor nearly doubled, and average days of COX-2 medication per user increased significantly from 1999 to 2000. This growth is dramatic considering this is not an elderly population. At $2.40 per medicated day, the annual cost per insured user (including insurer and patient payments) averaged

nearly $250. A therapeutic dose of a traditional NSAID would have cost $.50 per day and $52 annually – an average cost savings of 79 percent per patient.[13] Although less than 1 of every 25 NSAID users in this population is at risk for GI bleeding, 1 in every 7 NSAID users was prescribed a COX-2 inhibitor. The vast majority of these users could have obtained the same pain relief with a traditional NSAID. For patients without insurance and/or with more days of use, the savings would be even greater.[14]

Second-generation systemic antihistamines, such as Allegra, Claritin, and Zyrtec are another class of drugs that has been heavily advertised to consumers by manufacturers. Makers of second-generation antihistamines assert the drugs are as effective as traditional antihistamines without the sedating side effect. Whether the drugs are non-sedating or merely less sedating is debatable, but the price difference compared to traditional antihistamines is not – second-generation antihistamines are much more expensive. Use of these drugs grew significantly among children, teens, and non-elderly adults in the MCDB from 1999 to 2000, with a 25 percent increase among children under age 12. Many physicians are troubled by the increased use of these antihistamines since current practice standards call for treating the underlying cause of allergic rhinitis – inflammation – instead of just the symptoms addressed by antihistamines. The first line of treatment for allergic rhinitis is use of nasal steroid sprays, such as Nasarel, Beconase, or Flonase, which reduce, if not eliminate, the symptoms for which patients seek relief through antihistamines. At $1.82 per medicated day, the expenditure for second-generation antihistamines per user in the MCDB averaged nearly $160 in 2000. Excluding the few patients unable to use nasal steroids for medical reasons, adults using Nasarel at the standard dose for the same number of days would have paid about $137 to treat the underlying cause and avoid the issue of sedation altogether.[15] For children and teens using half the adult dosage (and for fewer days per year), Nasarel would have averaged $58 annually, less than half the cost associated with their use of second-generation antihistamines.

Impact on Prescription Insurance

The continuing rise of prescription drug costs has become a major issue of concern for many health plans offering prescription drug coverage, as well as for employers, Medicare beneficiaries, and Medicaid enrollees.

Private – Private health plans have responded with strategies aimed at offering consumers broader choices while shifting more costs to consumers based on those choices. These include a mix of cost-sharing approaches such as tiered co-payments, drug selection (brand-name vs. generic), and negotiated discount pricing. Many plans have established three-tiered benefit design packages that allow consumers to pay the lowest out-of-pocket costs for generic drugs, higher costs for brand-name drugs, and the highest costs for brand-name drugs not on a formulary. National figures indicate that the proportion of health plans offering three-tiered drug benefits increased from 36 percent in 1999 to 80 percent in 2000.[16] Other strategies under consideration by plans include annual caps on prescription drug coverage, reference pricing based on a fixed monthly benefit limit, a pharmacy deductible, and active campaigns aimed at impacting the influence of direct-to-consumer advertising on prescription drug costs.

Medicare – Because traditional Medicare does not provide outpatient prescription drug coverage, two-thirds of Medicare beneficiaries must rely on drug coverage from either a private Medigap insurance policy, an employer-sponsored retirement plan, a Medicare+Choice plan, or Medicaid.[17] The remaining one-third of beneficiaries have no coverage at all. The greatest interest among most seniors is to purchase a Medicare+Choice plan to fill the gap in prescription drug coverage. Nationwide, however, many Medicare health insurers are raising co-payments, placing new limits on drug payments, or eliminating drug coverage completely in order to halt huge financial losses even as the supply of Medicare+Choice plans is decreasing.[18] Only two health plans, Kaiser Permanente and Elder Health offered Medicare+Choice products in Maryland at the start of 2001, with a monthly premium ranging from $79 to $99 for prescription drug coverage.[19]

Federal policy makers, consumer groups, and pharmaceutical companies agree that the elderly need prescription drug benefits. Most believe that some form of Medicare program expansion is the vehicle. Comprehensive proposals that add prescription drug benefits to Medicare have not gotten far because of disputes about the benefit structure and source of funding. Although philosophical differences contribute to the lack of consensus, the rapid growth in overall prescription drug spending adds uncertainty about the long-term cost of a drug benefit. Given the funding questions and renewed concerns about federal spending due to the economic downturn, more modest proposals may have greater prospects for passage in the 107th Congress.

Medicaid – In contrast to Medicare, state Medicaid programs offer prescription drug coverage to their beneficiaries. To combat rising prescription drug costs, many state governments are forming purchasing pools that would cover Medicaid enrollees, as well as state employees, and are implementing cost-control measures that include co-payments, a limit on the number of prescriptions per enrollee, pre-authorization to physicians, and substitution of generics for brand-name medicines. However, because these and other cost-containment measures affect access to prescription drugs, many Medicaid beneficiaries have reported that they were unable to obtain all the drugs prescribed for them. In a recent study by the Center for Studying Health System Change, 26 percent of Medicaid beneficiaries ages 18-64 reported that they could not afford to purchase all of their prescriptions.[20] Many states are considering reducing their reimbursement rates under Medicaid, which currently pays pharmacists for the cost of the drug plus a flat fee. Many of the nation's largest drugstore chains have responded with proposals ranging from reducing pharmacy hours to completely re-evaluating their participation in Medicaid in those states considering reimbursement reductions. State officials are trying to find other cost-cutting options and negotiate better deals from drug manufacturers.

State & Private Initiatives – In 2000, Maryland launched the Short-Term Prescription Drug Subsidy Program, an initiative that provides up to $1,000 in drug benefits to Medicare beneficiaries that have incomes below $27,000 ($35,000 for a couple). CareFirst administers the program, which will continue until July 2003. The Maryland Health Care Foundation has launched a drug bank that makes certain drugs available free of charge to eligible individuals. Pfizer, Eli Lilly, GlaxoSmithKline, and Novartis have created drug subsidy programs that allow the low-income elderly to receive discounts. These initiatives complement various Medicaid programs that provide drug benefits to eligible individuals.

S.C.O.R.E. (Standardized Calculator Of Risk for Events) This ulcer risk calculator is based on technology developed by Dr. Gurkirpal Singh and his colleagues at Stanford University Division of Immunology and Rheumatology and is licensed for educational purposes only. For licensing information or further details, please contact Dr. Singh at gsingh@stanford.edu. These calculations provide you with an approximate risk level for serious stomach complications when taking NSAIDs. Because this screener is based on assumptions which may or may not be applicable to you, a specific assessment should be obtained in consultation with your physician. Only your physician can decide if a particular treatment is appropriate for you.

1. How old are you?

Age 20 or less	0 points	Age 31-35	4 points	Age 46-50	8 points	Age 61-65	12 points	Age 76-80	16 points
Age 21-25	1 point	Age 36-40	5 points	Age 51-55	9 points	Age 66-70	13 points	Age 81-85	17 points
Age 26-30	3 points	Age 41-45	6 points	Age 56-60	10 points	Age 71-75	14 points	Age 86+	18 points

2. How do you self-rate your current health status on the following scale?
   Very Poor 4 points Poor 3 points Fair 2 points Well 1 point Very Well 0 points
3. Do you have rheumatoid arthritis (not osteoarthritis or other forms of arthritis)? No 0 points Yes 2 points
4. If you are taking prednisone or other corticosteroids by mouth (not by oral inhaler) or by injection, for how many months have you taken them in the past year?
   0 months 0 points 1-3 months 1 point 4-6 months 3 points 7-10 months 4 points 11-12 months 5 points
5. Have you ever been hospitalized for a GI bleed or an ulcer? (If "Yes," skip next question.) No 0 points Yes 2 points
6. (If answer to previous is "No") Have you ever had GI side effects (heartburn, stomach pain, nausea, vomiting) when taking NSAIDs?
   No 0 points Yes 2 points

What your S.C.O.R.E. means:

Risk level 1 **Up to 10 points:** Risk of a serious GI side effect (e.g., stomach ulcer or bleeding) is *not significantly increased* by taking NSAIDS, if taken as recommended in product labeling.

Risk level 2 **11 to 15 points:** Risk of a serious GI side effect (e.g., stomach ulcer or bleeding) is *moderately increased* by taking NSAIDS. Consultation with a medical professional is recommended for these patients, especially if they need to take NSAIDs regularly.*

Risk level 3 **16 to 20 points:** Risk of a serious GI side effect (e.g., stomach ulcer or bleeding) is *significantly increased* by taking NSAIDS. Consultation with a medical professional is advisable for these patients.

Risk level 4 **Over 20 points:** Risk of a serious GI side effect (e.g., stomach ulcer or bleeding) is *substantially increased* by taking NSAIDS. Consultation with a medical professional is strongly encouraged for these patients.

To illustrate what <u>might</u> be suitable first choice medications (using the lowest effective dose for the shortest effective period) for persons in each risk category, MHCC developed the following list from conversations with physicians expert in prescribing anti-inflammatories. A recent medication guideline for arthritis pain suggests non-NSAIDs for persons with mild-to-moderate pain (acetominophen) or severe pain (narcotic analgesics).

*<u>Risk level 4</u>: chronic use- Cox-2 selective agent; short-course, occasional use - low-risk NSAID***

*<u>Risk level 3</u>: chronic use =average risk NSAID+GI medication or low-risk NSAID**; short-course therapy, occasional use - average-risk NSAID**

*<u>Risk levels 1 & 2</u>: average-risk NSAIDs**

** includes familiar NSAIDs such as aspirin, ibuprofen, diclofenac, naproxen ** includes salsalate, etodolac, nabumetone, sulindac*

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[1] National Association of Chain Drug Stores (NACDS). *The Chain Pharmacy Industry Profile (1999, 2000, and 2001).* MHCC analysis of estimated retail sales of prescription drugs provided by NACDS. Maryland (MD) and District of Columbia (DC) pharmaceutical sales are derived from total store sales in MD and DC and assume that prescription drug shares of the total sales are the same as national averages. Unless otherwise noted, this report is the source for figures cited in this expenditure profile.

[2] More than 56 percent of MD+DC's 2000 non-mail order sales (in dollars) were made by chain drug stores. Sales through supermarkets accounted for nearly 23 percent of sales, followed by independent drug stores at 13 percent and mass merchants at 8 percent. This differs from the sales pattern across the US, where chain pharmacies accounted for nearly one-half (49.7%), independent drug stores one-fourth (25.4%), supermarkets 14 percent, and mass merchants 11 percent.

[3] Because of border crossing, purchases by residents of Maryland (MD) and the District of Columbia (DC) account for some of the sales for both jurisdictions. Estimates for MD and DC are combined to compensate for growth in MD and DC sales due to increased purchases by border-crossing residents.

[4] Nationwide mail order sales have been steadily increasing each year, from 13% in 1998 to 15% in 2000.

[5] Data analysis of the Commission's Medical Care Data Base, calendar year usage in 1999 and 2000. Utilization analysis is limited to those with at least one prescription covered by insurance. Information on enrollees without utilization is not submitted to the Commission.

[6] National Institute for Health Care Management, *Prescription Drug Expenditures in 2000: The Upward Trend Continues.* May 2001.

[7] Examples are BuSpar and Clarinex. Just as BuSpar, an anti-anxiety drug, was to expire, its manufacturer obtained a patent on what the drug becomes when it's swallowed. The manufacturer claimed generics for the original BuSpar would violate its new patent and was able to prevent generics from entering the market for four months until a court ruled in favor of the generic companies. The manufacturer of Claritin obtained a patent on desloratadine (Clarinex), the chemical produced by the body from loratadine, the drug in Claritin. Claritin will become an over-the-counter drug in 2003, so there will be no generic prescription version of loratadine/desloratadine until the patent on descloratadine expires.

[8] NSAIDs are used to reduce pain due to inflammation, as in osteoarthritis. Traditional NSAIDs include all NSAIDs except the new "COX-2 inhibitors," which reduce joint inflammation, and therefore pain, by acting on the COX-2 enzyme which causes joint inflammation.

[9] National Institute for Health Care Management, *Prescription Drugs and Mass Media Advertising.* November 2001.

[10] Wall Street Journal, March 25, 2002, p.R8; ABC News Special, May 29, 2002.

[11] Juni P, Rutjes AWS, Dieppe PA. "Are selective COX-2 inhibitors superior to traditional non-steroidal anti-inflammatory drugs?". British Medical Journal. 2002 June;324:1287-8.

[12] See the S.C.O.R.E. screening questionnaire on this page. Note that being elderly contributes far more risk than any other factor.

[13] The alternative medication is 800 mg of ibuprofen three times a day, at the average cost per 800 mg pill in the MCDB.

[14] The price gap between COX-2s and traditional NSAIDs for an insured patient is below the reported 8-10 multiple because insurers are able to obtain COX-2s at a considerable discount through agreements with manufacturers.

[15] The standard dose is adults: 2 sprays per nostril, 3 times a day, and children: 1 spray per nostril, 3 times a day.

[16] *2000 Managed Care Formulary Drug Audit.* Scott-Levin (2001).

[17] Blue Cross Blue Shield. *Issue Brief: Prescription Drugs for Seniors.* Available on the Internet at http://bcbshealthissues.com/issues/seniors.vtml

[18] Freudenheim, Milt. The New York Times. *Many HMOs for the Elderly Cut or Abolish Drug Coverage.* January 25, 2002.

[19] State of Maryland. Maryland Health Care Commission. Spotlight on Maryland. *"Escalating Health Care Costs, Rising Premiums Depress HMO Enrollment".* April 2002.

[20] Cunningham, Peter J. *"Prescription Drug Access: Not Just a Medicare Problem".* Center for Studying Health System Change. Issue Brief. April 2002.